PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

M. ALIZON et al.

Application No.: Not yet assigned

Filed: November 15, 2001

For: CLONED DNA SEQUENCES RELATED TO THE ENTIRE GENOMIC RNA OF HUMAN IMMUNODEFICIENCY VIRUS II (HIV-2), POLYPEPTIDES ENCODED BY THESE DNA SEQUENCES AND USE OF THESE DNA CLONES AND POLYPEPTIDES IN DIAGNOSTIC KITS

Prior Application Group Art Unit: 1648

Prior Application Examiner: Parkin, J.

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

PRELIMINARY AMENDMENT

Prior to the examination of the this application, please amend this application as follows:

IN THE CLAIMS:

Please cancel claims 1-43.

Please add claims 44-46 as follows:

--44. (New) A method for producing a polypeptide of HIV-2 having the amino acid sequence, which is encoded by at least a portion of a *pol* gene as set forth in

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Figure 6, comprising providing a transformed host containing a DNA coding for the polypeptide and expressing the polypeptide.

45. (New) An isolated nucleic acid of HIV-2 having at least a portion of the nucleic acid sequence of a *pol* gene as set forth in Figure 6.

46. (New) A nucleic acid of HIV-2 as claimed in claim 45, wherein said nucleotide sequence is a sequence that hybridizes with at least one domain in a *pol* gene of HIV-1_{BRU} in a hybridization solution comprising 50% formamide, 5X SSC, 5X Denhardt solution, 10% dextran sulfate, and 100µg/ml denatured salmon sperm DNA for 16 hours at 42°C with 2 washes for 30 minutes in a solution of 0.1X SSC and 0.1% SDS.--

REMARKS

Claims 44-46 are now pending in this application. In the parent application, these claims were rejected as lacking written description support.

The Examiner seemed concerned that the specification recites particular fragments for the Gag and Env proteins in Example 6, but that the specification does not provide a sequence for a particular pol fragment. The Examiner does not seem to dispute that the specification provides support for (1) the full length pol sequence and (2) the concept that fragments were considered to be part of the invention. What the Examiner appears to require, instead, is a listing of particular pol fragments, along with their sequences, in the specification in order to allow a pol fragment claim.

The Examiner's standard is higher than the law requires. The Examiner cites cases such as *Utter v. Hiraga*, 6 U.S.P.Q.2d 1709 (Fed. Cir. 1988), *Ralston Purina Co.*

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v. Far-Mar-Co., 227 U.S.P.Q. 177 (Fed. Cir. 1985), *In re Rasmussen*, 211 U.S.P.Q. 323 (C.C.P.A. 1981), and *In re Wertheim*, 191 U.S.P.Q. 90 (C.C.P.A. 1976), for the proposition that the inventors must have had possession of the claimed invention at the time the application was filed. The Examiner seems to interpret these cases as requiring that the inventors were in physical possession of fragments of the pol gene and that the specification contain examples using the pol fragments as it has with the gag and env fragments.

None of the cited cases require that the inventors had a physical or actual reduction to practice of the claimed invention. It only requires that the inventors described the limitation as part of their invention. As constructive reduction to practice is sufficient for conception, it also can provide written description support for an invention. Applicants have stated in the specification that fragments are part of the invention. The Examiner has not pointed to any specific statements that exclude fragments of pol from the invention. As Applicants have described fragments as being part of their invention, without limitation, the mere fact that Applicants have enumerated particular fragments of env and gag does not mean that the general disclosure of fragments does not apply to pol.

Furthermore, it is not necessary to provide particular sequence information on the fragments included in the invention. The disclosure of the full length pol satisfies the requirements set forth by recent description cases, such as *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). That case required structural definitions of claimed DNA's, such as with sequence data. Here, as the inventors

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provided the full length sequence of pol, the fragment sequences can be deduced from the full length sequence. This is not a violation of the written description requirement, as the specification does not have to provide *ipsis verbis* descriptions of the limitation to satisfy the description requirement. *Union Oil Co. of Calif. v. Atlantic Richfield Co.*, 54 U.S.P.Q.2d 1227, 1235 (Fed. Cir. 2000).

In conclusion, Applicants believe that the specification supports the concept of fragments, and does not limit it to those set forth in the Examples.

If there is any fee due in connection with the filing of this Preliminary Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: November 16, 2001

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